DETERMINATION OF CONFORMANCE WITH SPECIFICATIONS USING MEASUREMENT UNCERTAINTIES – POSSIBLE STRATEGIES

Introduction

Conformity assessment is a common activity performed in testing, inspection and calibration, required to assure the compliance of products, materials, services and systems to requirements defined by standards, regulations, legal frameworks and contract agreements, being defined to establish confidence for consumers and for the safety and quality of life. Today, it has a major impact on the global economy as it implies the acceptance and rejection of items directly affecting risk analysis, business decisions, and reputational and financial costs.

In the evaluation of compliance, which is based on quantitative results, different scenarios can be considered, which can be illustrated in 4 case studies (cases A to D, see Figure 1). In this, cases A and D are unambiguous as the decisions are not influenced by the measurement uncertainties. However, in cases B and C where the measurement uncertainty interval is overlapping the limit value, careful analysis that should establish objective criteria (decision rule) is required to accept results that are outside the tolerance with part of the measurement uncertainty interval.

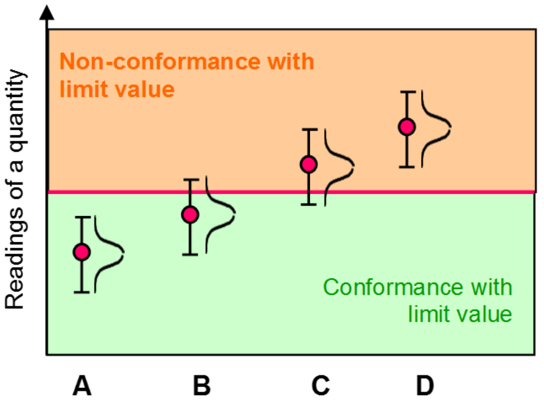

Fig. 1: Test results and their measurement uncertainties in relation to an upper limit value

A general approach to conformity assessment

Decisive for a suitable definition of a decision rule is the question of what should be proved with the conformity assessment: compliance or non-compliance with a specification or a limit value. Based on the answer, either the supplier’s risk (α) or the consumer’s risk (β) has to be specified.

Defining a procedure to perform the conformity assessment may be based on the following steps:

a. The specification of a measurand (Y) and the measurement item to be tested.

b. The experimental / analytical results (estimates y of the measurand Y).

c. The measurement standard uncertainty, $u(y)$, and for a certain confidence level, the expanded measurement uncertainty.

d. The specification of a single tolerance limit (upper or lower) or tolerance interval limits.

e. The definition of the acceptance zone, rejection zone and a guard band assuming a probability of type I error (supplier’s risk α) or type II error (consumer’s risk β).

f. A decision rule.

The terminology adopted is described in known references, [EURACHEM Guide:2007], [ASME B89.7.3.1:2001] and [EUROLAB Technical Report 1/2017]. Two of these are particularly relevant.

- **Decision rule**: a documented rule that describes how measurement uncertainty will be allocated with regard to the acceptance or rejection of a product according to its specification and the result of a measurement.
- **Guard band**: the magnitude of the offset from the specification limit to the acceptance or rejection zone boundary.

Establishing the decision rule

In the event that regulations or normative standards contain provisions for compliance with specifications or limit values taking into account measurement uncertainties, these provisions have to be applied. If such provisions are missing, rules have to be established prior to testing to meet market or safety requirements.

The international standard ISO 14253:2016 part 1: *Decision rules for proving conformance or non-conformance with specifications* distinguishes whether conformance or non-conformance shall be determined with a high degree of probability. The expanded measurement uncertainty *U* and a confidence level of approx. 95% (coverage factor k = 2) is generally considered adequate. Only in exceptional cases a higher confidence level of e.g. 99% (coverage factor k = 3) is chosen.

The determination of decision criteria should take into account whether the specification is an interval or a limit (upper or lower), whether guard bands should be considered and, if so, whether they should reduce or enlarge the acceptance interval. The following Figures illustrate various possibilities (where T_U – tolerance upper limit; G_U – guard band upper limit, T_L – tolerance lower limit, G_L – guard band lower limit, $U(y)$ – expanded uncertainty of the measurement.

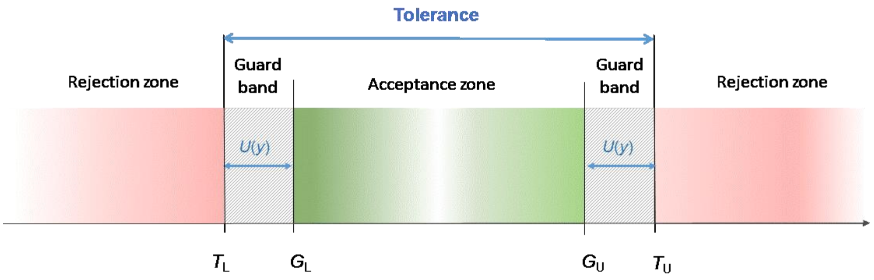

Figure 2 – Example of areas defined for a tolerance interval in order to minimise the consumer’s risk

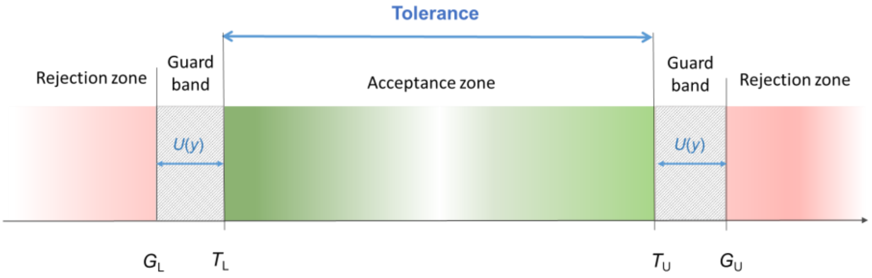

Figure 3 – Example of areas for the tolerance interval in order to minimise the supplier’s risk

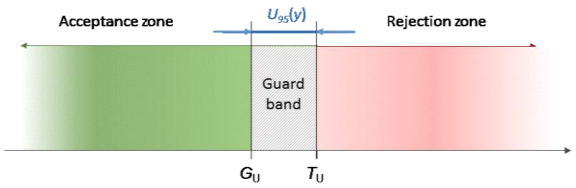

Figure 4 – Guard band for upper tolerance and guarded acceptance defined with a confidence level of 95%

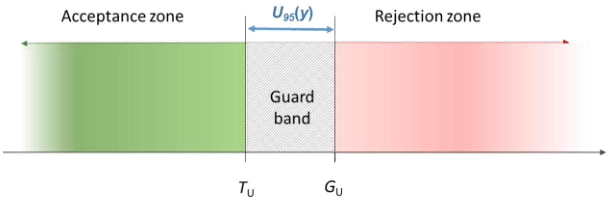

Figure 5 – Guard band for upper limit and guarded rejection

In the case where guard bands are used, in particular for measurement results with the same uncertainty, it may be a simple strategy to establish a decision rule by comparing the measurement results with the acceptance zone limits, where the measured value must be within these acceptance zone limits, otherwise rejected.

If the measurement results have different measurement uncertainties, it is recommended to consider an approach without guard bands.

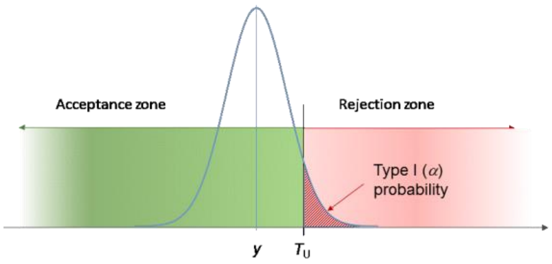

Figure 6 – Example with single upper tolerance

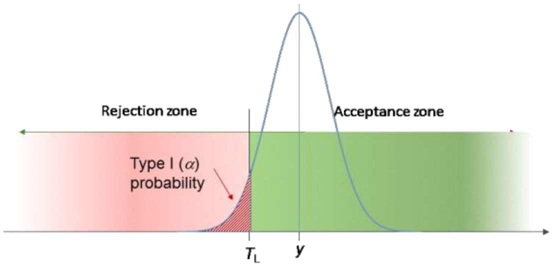

Figure 7 – Example with single lower tolerance

In these cases, the criteria may be established by performing a hypothesis test where fulfilment of the H_0 condition implies the decision of acceptance and, otherwise, implies the decision of rejection. Therefore, assuming the probability of type I error (α), the decision rule can be expressed as:

Decision rule

Acceptance, if the hypothesis H_0: $P(Y \leq \mathrm{T}_U) \geq (1-\alpha)$ is true;

Rejection, if the hypothesis H_0 is false, $P(Y \leq \mathrm{T}_U) < (1-\alpha)$.

Expression to test: $P_\mathrm{C} = P(\eta \leq T_\mathrm{U}) = \Phi\left(\frac{\mathrm{T}_\mathrm{U}-y}{u(y)}\right)$

The following is a pratical example of application :

Consider a measurement estimate of y = 2,7 mm with a measurement uncertainty of $u(y)$ = 0,2 mm, a single tolerance upper limit of T_U = 3,0 mm, and a specification of conformity (1 – α) of 0,95 (95 %) and thus assuming a type I error of α = 0,05 (5%).
With the experimental result and the tolerance limit, assuming a normal PDF (Probability Distribution function), the decision rule will be as follows:

Acceptance, if the hypothesis H_0: $P(Y \leq 3{,}0\ \mathrm{mm}) \geq 0{,}95$ is true

Rejection, if the hypothesis H_0: $P(Y \leq 3{,}0\ \mathrm{mm}) \geq 0{,}95$ is false

To estimate the probabilities for the given example, the conformance probability (P_c) need to be calculated using the general expression for normal PDFs:

$$P_\mathrm{C} = P(\eta \leq T_\mathrm{U}) = \Phi\left(\frac{\mathrm{T}_\mathrm{U}-y}{u(y)}\right)$$

$$P_\mathrm{C} = \Phi\left(\frac{3{,}0-2{,}7}{0{,}2}\right) = \Phi(1{,}5) \approx 0{,}933 \text{ (93,3 \%)} < 0{,}95$$

Thus, the hypothesis H_0 is false and the decision to be taken is rejection (non-compliant).

Note:
The value of $\Phi(z)$ can be obtained by using tables of standard Gaussian PDF or by software having functions to perform this type of calculations, e.g.:

MS Excel function NORMDIST (x, mean, standard deviation, cumulative), for the case described above is: NORMDIST(3,0;2,7;0,2;TRUE) and would be the result (0,933).

Literature:

- ISO 14253-1: Geometrical product specifications (GPS) - Inspection by measurement of workpieces and measuring equipment - Part 1: Decision rules for verifying conformity or nonconformity with specifications (2017)
- EURACHEM Guide: Use of uncertainty information in compliance assessment (2007)
- ASME B89.7.3.1: Guidelines for Decision Rules: Considering Measurement Uncertainty, Determining Conformance to Specifications (2001)
- EUROLAB Technical Report 1/2017: Decision rules applied to conformity assessment (2017)
- ISO/IEC Guide 98-4, Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment (2012)